

REMARKS

Status of Claims

Claims 2-4, 9-12, 17, and 19-44 are pending.

Claim Rejections: 35 U.S.C. § 102

Claims 34-44 were rejected under 35 U.S.C. § 102(e) as encompassing subject matter anticipated by Michelson US 2002/0002474-A1.

Claim 34 is patentable to Knight over Michelson because Knight's provisional application supports the claim and Michelson's does not. Knight therefore has the earlier filing date for the claim.

Knight's provisional application (ser. no. 60/227,484) was filed Aug. 24, 2000 and supports the claimed subject matter, as discussed below. Although Michelson's provisional application was filed before that (ser. no. 60/178,634, filed Jan. 28, 2000), it does not support the subject matter of claim 34, and Michelson's PCT application (PCT/US2001/002936, filed Jan. 29, 2001) was filed too late to be prior art to Knight's provisional application. A copy of Michelson's provisional application is appended to this response as "Exhibit A" for the Examiner's convenience.

Among other things, the claim requires that the computer memory store "information indicating whether notice of one or more clinical studies associated with a particular disease condition is desired." The only patient information Michelson's provisional application describes storing is "relevant clinical data, zip code of residence,

and e-mail addresses” (p. 7, first full paragraph). Michelson does not disclose storing information about a patient’s interest in being contacted. The system described in Michelson’s provisional application is one in which the investigators or drug companies mine the patient database to identify candidate patients, whom they then contact unilaterally. Michelson does not address the patient’s desire in this regard, only the investigator’s and drug company’s.

Knight’s provisional application, in contrast, specifically addresses storing information about whether a patient wants to be contacted. See, for example, Fig. 2 on p. 9 of Knight’s provisional application, which shows an example of a questionnaire allowing patients to elect whether they want to be contacted about future clinical trials or instead to remain anonymous. So claim 34 is supported by Knight’s provisional application and not anticipated by Michelson’s provisional application. Michelson is therefore not prior art under 35 U.S.C. § 102(e), and claims 34-44 are patentable over it.

Claim Rejections: 35 U.S.C. § 103(a)

Claims 2-4, 9-12, 17, and 19-33 were rejected under 35 U.S.C. § 103(a) as encompassing subject matter unpatentable over Michelson US 2002/0002474-A in view of Reddy WO 01/93160-A1.

But the rejection cannot stand, because the rejected claims all find support in Knight’s provisional application, and Michelson’s provisional patent application lacks disclosure of several claim limitations relied upon by the Examiner.

Claim 19 and its dependent claims

Claim 19 finds support in Knight’s provisional application as shown in the following claim chart.

Element of Claim 19	Support in 60/227,484
19. A computer system for recruiting a patient into a clinical trial, the system comprising components configured as at least:	Page 1, Title: "Interactive Internet Clinical Trial Patient Recruitment."
a server which:	Page 13, Fig. 5: "Web Application Server"
requests patient-specific data from the patient,	Page 7, bottom: "The questions presented in the second level of the My Clinical Trials form are determined by the patient's response in level one." Page 10, Fig. 3 shows second-level questions requesting patient-specific data.
the patient-specific data requested including clinical trial eligibility data;	Page 7, bottom: "Finally, in level 4, the patient is presented with any unanswered questions applicable to a selected trial's eligibility criteria, ensuring that the patient fully meets a trial's eligibility."
collects the patient-specific data from the patient; and	Page 4, third paragraph under Summary: "Once the My Clinical Trials data is submitted . . ."
Sends match result data to the patient;	Page 10, bottom: "Once the match results are sanitized by the security application, the appropriate match results are displayed to the patient." Page 11, Fig. 4 shows match results displayed to the patient.
a matcher	Page 14, last paragraph: "matching algorithm"
responsive to the patient's clinical trial eligibility data and to trial-specific criteria corresponding to the clinical trial to:	Page 14, last paragraph: "a sophisticated matching algorithm compares the patient's data to the clinical trial eligibility data."
determine whether a match exists between the patient and the clinical trial; and	Page 8, lines 1-3: "Veritas considers a patient to be a 'match' for a trial if the data submitted via the My Clinical Trials form successfully passes enough of a trial's eligibility criteria to meet the specified match percentage determined by the pharmaceutical company or trial site."
generate the match result data; and	Page 17, line 1: "When match results are determined, . . ."
a security layer which:	Page 13, Fig. 5: "Security Application"
prevents direct communication between the	Page 13, Fig. 5: Web Application Server is separated from databases by Security Application. Page 17, lines 1-2:

Element of Claim 19	Support in 60/227,484
server and the matcher;	“When match results are determined, the security application layer also sanitizes the information passed on to the client system.”
receives the patient-specific data from the server;	Page 13, Fig. 5: depicts server receiving communication from Internet. Page 15, first paragraph under “Fine-Grained Access Control”: “The security application protocol is designed to accept requests from particular machines (e.g., the web server wants a patient to clinical trial match) . . .”
sends the patient’s clinical trial eligibility data to the matcher; and	Page 15, first paragraph under “Fine-Grained Access Control”: “Then, the [security] application passes this validated request on to the appropriate database . . .”
receives the match result data from the matcher and sends it to the server.	Page 15, first paragraph under “Fine-Grained Access Control”: “. . . and assembles an appropriate answer for the web server’s question.”

Because Applicant’s claim is entitled to a priority date that predates Michelson’s nonprovisional application, the patentability analysis must focus on Michelson’s *provisional* disclosure, not his nonprovisional disclosure. The Examiner took the position that Michelson teaches every element of claim 19 except the recited security layer. But this cannot be so, because Michelson’s provisional application does not teach each of those elements and, in fact, teaches away from the claimed security layer.

A. Michelson’s provisional application does not teach a server which requests or collects patient-specific data from the patient.

Michelson’s provisional application describes no interaction between a patient and a computer system except the “Tier 1”-level access discussed in the second full paragraph of page 8, which includes “general information about the pharmaceutical industry, industry specific news, and clinical trials” and also provides “chat rooms that will give patients a location to ask questions of research investigators and of other patients.” The Michelson provisional application never describes requesting or collecting

any patient-specific data from a patient that is subsequently used by the matcher. While the Michelson provisional application does describe “account sign-up, management, demographics capture, and personalization of target audiences” in the second full paragraph of page 9, it never describes the collection of any data that is subsequently used for matching, nor does it even specify that such “account sign-up” etc. is carried out by a patient. Indeed, the end of the paragraph states that the system is customized to particular “sponsors,” which indicates that the users who are setting up accounts are from pharmaceutical companies sponsoring clinical trials, not patients seeking recruitment. And while the provisional application mentions that its software “enables patients to identify clinical trials for which they may enroll” at p. 10, lines 4-5, this disclosure simply refers to the general public’s ability to browse “general information about . . . clinical trials” available through the Tier-1 access discussed on page 8. It does not suggest any kind of matching that is responsive to clinical trial eligibility data collected from a patient.

Moreover, Michelson expressly states the sources of patient data, in the first full paragraph of p. 7 of his provisional application, all of which are non-patient third parties:

[The patient] database is created through solicitations in advertisements on other Internet sites, through collection of billing and other data from the physician practice management systems of the physician investigators who have private practices, and through managed care organizations, employers, hospital systems, prescription benefit manager, disease management companies, disease advocacy groups, and physician practice management companies. Further information may be collected from pathology labs to provide more detail about the disease status of oncology patients.

Furthermore, in referring to “collection of billing and other data” from management systems, managed care organizations, employers, hospital systems, etc.,

Michelson clearly espouses his intent to gather patient data in bulk from organizations that maintain large repositories of patient data, rather than by piecemeal one-on-one interactions with patients.

B. Michelson's provisional application does not teach a server which sends match result data to the patient.

Because, as noted above, Michelson's system does not communicate anything to a patient other than the "general information about the pharmaceutical industry, industry specific news, and clinical trials" etc., available through Tier-1 access, it follows that Michelson never sends match result data to the patient. Rather, it is the investigators who conduct the searches, obtain the results, and decide whether to contact patients; the system "enables clinical trial investigators and sponsors to identify individuals in the patient database who have a likelihood of qualifying for a particular clinical trial" (p. 9, last two lines). *Patients* do not carry out this identification. Indeed, they cannot, because Michelson's provisional disclosure restricts database access to only Tier 2 users "confirmed to be in the pharmaceutical industry" and Tier 3 users, who are "sponsors of clinical trials" (p. 8, last paragraph). Thus, Michelson's provisional system does not conduct matches at the behest of patients and does not communicate any match result data to them.

C. Michelson's provisional application teaches away from the claimed security layer.

Michelson's provisional application states in the very first paragraph (p. 1, line 6) that its system is designed "to enable appropriate parties **access and use of the secure databases**" (emphasis added). Michelson's provisional application repeatedly states that the system is designed to give authorized users access to the databases (*see* p. 8, last

paragraph, and p. 10, last paragraph). Yet the claimed security layer specifically excludes such database access by preventing direct communication between the server and the matcher. By requiring that authorized users have direct access to the secure databases, Michelson's provisional application unambiguously deters the reader from interposing the claimed security layer.

Claim 17

Arguments analogous to arguments (A) and (C) given above for claim 19 apply to claim 17.

In addition, Michelson's provisional application does not teach registering a patient in a database *after* clinical trial criteria have been determined to be satisfied, as required by claim 17. Instead, Michelson's provisional application describes building up a patient database *before* searching that database to identify patients located near an investigator. Michelson never describes sending patient-specific data to a database only after determining whether a match exists between a patient and a clinical trial.

Moreover, Michelson's nonprovisional disclosure underscores his express requirement that patients first be registered *before* any access to clinical trials is provided. *See*, for example, Figs. 2A-2B, in which one of the benefits of registration is to "get trial information and find out how you can be considered for participation in clinical trials," and paragraphs [0082]-[0083], which explain that only registered users may attempt to qualify for clinical trials. For example, in paragraph [0082] Michelson states that "demographic information about each registered person is stored in the database" and then states that as a person "attempt[s] to qualify for participation in various clinical studies, system 100 collects and stores additional information about the persons

represented in the subject database,” meaning that a person is *already registered* in the database when seeking to qualify for a clinical trial. In contrast, the claim specifies that registration occurs *after* clinical trial criteria have been determined to be satisfied. The difference is non-trivial; Applicant’s claimed system affords a greater deal of privacy to patients compared to Michelson’s system by allowing them to attempt a trial match before revealing any personal identification.

Claim 23

Arguments analogous to arguments (A) and (B) given above for claim 19 apply to claim 23.

With respect to claim 25, Michelson’s provisional application does not disclose registering a patient in a database after a match has been determined to exist, for reasons analogous to those given above for claim 17.

Claim 31

Arguments analogous to arguments (A) and (B) given above for claim 19 apply to claim 31.

In addition, Michelson’s provisional application does not teach conducting a second match operation for a particular trial if a first match is determined to exist for multiple trials.

Claim 31 recites a two-stage match procedure in which a first set of patient eligibility data is compared to general trial criteria for a plurality of trials, and then, if a match exists, a second set of patient eligibility data is compared to specific trial criteria for one trial. The second match is tested only if the first match exists, and the patient is given information about the one trial only if both matches exist. These features are

supported by Applicant's provisional application (*see*, for example, Fig. 1 on p. 7, which shows Level 3 questionnaire data being screened against a plurality of trials, followed by Level 4 questionnaire data being screened against one trial).

As noted previously, Michelson's provisional application does not even disclose a one-stage match procedure which involves communication with a patient. Michelson's provisional application does not disclose a two-stage match procedure of any kind.

Reddy's disclosure does not supply the elements missing from Michelson's provisional application. Consequently, the combination of Michelson and Reddy does not reach the subject matter of the rejected claims. Moreover, Michelson's provisional application teaches away from the security layer of claims 17, 19, and claims dependent thereon by requiring that users be able to access the databases, so Michelson may not be combined with Reddy in the manner the Examiner has suggested.

For these reasons, Applicant asks the Examiner to reconsider and withdraw all rejections.

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